pHoenix Diagnostics, Inc.
8 TECH CIRCLE • NATICK, MA 01760 • TEL: 508-655-8310 • FAX: 508-655-8273

DEC 1 8 2001

K013451

510 K SUMMARY

pHoenix ISE Reagents for Roche/Hitachi Models 700/900 Series.

1. Submitter: Ram Nunna.

Address: pHoenix Diagnostics, Inc.
8 Tech Circle
Natick, MA. 01760

Phone: 508-655-8310

Fax: 508-655-8273

Contact Person: Ram Nunna

Date of Summary: 11/9/01

2. Device Name and Associated Information:

Device name: pHoenix ISE Reagents for Roche/Hitachi 700, 900 series.

Trade name: Same as above.

Common name: Same as above.

Classification and Associated Information:

Classification: Calibrator, Multianalyte Mixture.

Device Classification: Class II

Panel: Chemistry 75

Product Code: JIX

3. pHoenix ISE Reagents for Roche/Hitachi 700/900 Series Clinical Chemistry Systems are similar in composition and performance to Roche Diagnostics equivalents.

Attachment: Substantial equivalence comparison.

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510 K Summary:

pHoenix ISE reagent for Roche Hitachi Clinical Chemistry 700 and 900 Series Systems:

pHoenix Diagnostics, Inc. is submitting a 510 (K) notification for the following: (1) pHoenix ISE Diluent, (2) ISE Internal Reference Solution and (3) ISE Low and High Standards. These ISE Reagents are intended for use on the ISE Module of the Roche Hitachi Clinical Chemistry Systems. The ISE Diluent dilutes all measured patient samples for the quantitative determination of Na^+, K^+ and Cl^- in serum by ISE. The ISE Internal Reference Solutions are intended as a means of compensating for calibration drift in the quantitative determination of Na^+, K^+ and Cl^- in serum samples on the Roche Hitachi Clinical Chemistry Systems. The ISE High and Low Standards are intended to provide calibration points for the Na^+, K^+ and Cl^- Electrodes on the ISE system. pHoenix Diagnostics, Inc. is claiming substantial equivalence to predicate devices manufactured by Roche Diagnostics Corporation. These reagents are intended to serve as a direct replacement to like named products manufactured by Roche Diagnostics. pHoenix uses a similar composition description and packaging design as used by Roche Diagnostics. pHoenix has shown performance equivalence of its products to Roche Diagnostics products in the following manner:

1. Through method comparison
2. Through precision study

pHoenix Diagnostics, Inc.
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Intended Use:

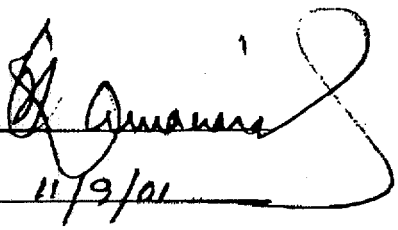
The pHoenix ISE Reagents for Roche Hitachi 700/900 series are intended for use as ISE Reagents for the determination of Na^+, K^+ and Cl^- for the Roche Hitachi 700/900 series Clinical Chemistry Systems.

The ISE Diluent are intended for use as a diluent for patient samples for the quantitative determination of Na^+, K^+ and Cl^- in serum by ISE.

The ISE Internal Reference Solutions are intended as a means of compensating for calibration drift in the quantitative determination of Na^+, K^+ and Cl^- in a serum sample on the Roche Hitachi Clinical Chemistry Systems.

The ISE High and Low Standards are intended to provide calibration points for the Na^+, K^+ and Cl^- Electrodes on the Roche Hitachi ISE system.

Ram Nunna

Signature: 

Date: 11/9/01

K013451

510K Number

Email: tmccarthy@phoenixdiagnostics.com • Web: www.phoenixdiagnostics.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Ram Nunna
Contact Person
pHoenix Diagnostic Inc.
8 Tech Circle
Natick, MA 01760

DEC 1 8 2001

Re: k013451
Trade/Device Name: pHoenix ISE Reagents for Roche Hitachi 700/900 series
Regulation Number: 21 CFR 862.1665; 21 CFR 862.1600; 21 CFR.1170; 21 CFR 862.1150
Regulation Name: Sodium test system; Potassium test system; Chloride test system; Calibrator
Regulatory Class: Class II; Class II, Class II, Class II
Product Code: JGS; CEM; CGZ; JIX
Dated: October 15, 2001
Received: October 18, 2001

Dear Mr. Nunna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K_____

Device Name: pHoenix ISE Reagents for Roche Hitachi 700/900 series

Indications For Use:

Intended Use:

The pHoenix ISE Reagents for Roche Hitachi 700/900 series are intended for use as ISE Reagents for the determination of Na^+, K^+, and Cl^- for the Roche Hitachi 700/900 Series Clinical Chemistry Systems.

The ISE Diluent are intended for use as a diluent for patient samples for the quantitative determination of Na^+, K^+ and Cl^- in serum by ISE.

The ISE Internal Reference Solutions are intended as a means of compensating for calibration drift in the quantitative determination of Na^+, K^+ and Cl^- in serum samples on the Roche Hitachi Clinical Chemistry Systems.

The ISE High and Low Standards are intended to provide calibration points for the Na^+, K^+ and Cl^- Electrodes on the Roche Hitachi ISE system.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013451

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)
